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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,769	05/31/2001	Dennis M. Brown	A-70600/RFT/AMS	1226

7590 07/21/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,769

Applicant(s)

BROWN, DENNIS M.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for reconsideration received on May 16, 2003 is acknowledged.

Claims 1, 4-10, and 14 are pending.

Claim Rejections - 35 USC § 112

Rejection of claims 1, 4-10, and 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1, 4-10, and 14 under 35 U.S.C. 103(a) as being unpatentable over Francis (4,797,388) in view of Levin et al (Chemotherapeutic approaches to brain tumors) is maintained.

Response to Arguments

Applicant argues that there is no motivation to combine the references with an expectation of success. Applicant argues that Francis teaches the addition of galactitol to increase the stability of the therapeutic agent. The applicant argues that Levin teaches the combination of BCNU and DAG is more successful at treating brain tumors than either compound alone. It is argued that applicant is not claiming the alkylating agent BCNU. It is argued there is no motivation to substitute BCNU with instant

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antiproliferative agents. Secondly, applicant argues that a skilled artisan would not reasonably expect that the addition of DAG with one of the claimed antiproliferative compounds would result in a more successful anti-tumor treatment than either compound alone. Lastly, applicant argues that each reference addresses different problems.

Applicant's arguments have been fully considered but they are not persuasive. Firstly the examiner points out that the rejection is an obviousness type rejection. Therefore, the primary reference, i.e. Francis is relied upon to teach the broad aspect of the claimed invention. As set forth in the rejection, Francis teaches galactitol (1, 2: 5, 6-dianhydrogalactitol) in combination with antiproliferative agents. Several suitable antiproliferative agents including instant agents are taught on column 3, lines 1-16. Note that Francis teaches anti-cancer agents as the preferred active agent. See column 2, lines 60. Francis only lacks in teaching that the galactitol acts as an antiproliferative agent. The examiner relies on Levin et al to teach the antitumor activity of hexitol epoxides, especially DAG. Furthermore, as recognized by applicant, Levin teaches the effectiveness of combination therapy of an antiproliferative agent (BCNU) and DAG. Levin clearly states combination therapy to enhance the anti-tumor activity of DAG. Therefore, it would be obvious to look to Levin's teachings of combined therapy and the anti-tumor activity of hexitol epoxides and recognize that Francis's galactitol will function as an anti-tumor agent. Thus, utilizing Francis's galactitol composition for treating proliferative diseases.

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In regards to the argument that applicant is not claiming BCNU, the examiner points out that BCNU is an antiproliferative agent; therefore the expectation of similar activity of hexitol epoxides with other antiproliferative agents is reasonable.

In regards to the arguments that the references address different problems, the examiner points out that the use of patents as references is not limited to what the patentees describe as their own invention or the problems, which they are concerned with. See *In re Heck*. Therefore, although Francis is concerned with stabilizing anti-cancer agents, Francis does teach instant composition. Furthermore, it is obvious that when one incorporates an anti-cancer agent to make a pharmaceutical product, it is implicit that the product will be utilized for treating cancer without explicitly stating so. Levin teaches treating brain tumors, which is a proliferative disease. Thus, both references are analogous art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

Sharmila S. Gollamudi
July 15, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER